



Guidance Document: Registering as a 503B Outsourcing Facility

Updated 2-2-2017

Effective October 24, 2014, Ohio Administrative Code Rule 4729-16-02 permits entities, known as outsourcing facilities, to provide non-patient specific sterile compounded drug preparations for human use only. In order for an outsourcing facility to operate and/or conduct business in the State of Ohio all of the following apply:

- The entity must be registered with the United States Food and Drug Administration as an outsourcing facility pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act. More information on registering as an outsourcing facility can be accessed here: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm389118.htm>
- The outsourcing facility must be registered with Ohio as a Wholesale Distributor of Dangerous Drugs (WDDD) with an outsourcing facility classification. You will need to submit proof of registration with the FDA with your application. The Wholesale Distributor of Dangerous Drugs Outsourcing Facility Application can be accessed here: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>.

Please note: If you are planning to provide controlled substance sterile drug preparations, you must also fill out the application for a manufacturer of a controlled substance included in the WDDD application.

Q1) If an outsourcing facility dispenses patient specific drugs do they need to apply for a terminal distributor of dangerous drugs license?

Yes. Ohio Administrative Code 4729-16-02 requires an outsourcing facility that dispenses patient specific drugs must also register as a terminal distributor of dangerous drugs. Applications for terminal distributor licenses can be accessed here: <http://www.pharmacy.ohio.gov/Licensing/TDDD.aspx>

Please note: If you are planning to provide patient-specific controlled substance sterile drug preparations, you must apply for a category III license.

Q2) Does a registered pharmacist need to be the responsible person on the Wholesale Distributor of Dangerous Drugs license with an outsourcing facility classification?

Yes. Ohio Administrative Code 4729-16-02 requires a pharmacist to be the responsible person on the license.



Q3) What is the definition of an outsourcing facility?

"Outsourcing facility" means a facility at one geographic location or address that is engaged in anticipatory compounding of sterile drugs and complies with the United States Food and Drug Administration section 503B of the Federal Food, Drug, and Cosmetic Act. More information on outsourcing facilities can be accessed here:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm393571.htm>

Q4) If my company already has a Wholesale Distributor of Dangerous Drugs (WDDD) license, do I need to apply for a new license?

Yes. An application for a WDDD license for an outsourcing facility requires a new application and a new application fee.

Please note: If you are planning to wholesale drugs as well as operate as an outsourcing facility you should indicate this in the narrative section of your application. Should you obtain a WDDD for an outsourcing facility and decide to ONLY wholesale drugs, then you must notify the Board in writing of this change within 30 days.

Q5) The regulations are not effective until October 24, 2014, can I begin the application process now?

Yes. However, you may not engage operation as an outsourcing facility until you receive your WDDD license with an outsourcing facility classification.

Q6) Other than my FDA registration, do I need to submit any additional documentation with my application?

Yes. If you were inspected by the FDA, you should include a copy of the GMP Inspection Form along with your application. Also, if applicable, any corrective actions &/or follow up inspection reports (including any Form FDA-483, WARNING letters, recalls, etc.) must be included with your application.

If you are an outsourcing facility located outside of Ohio, you will also need to submit proof of your outsourcing facility license from your home state and include a copy of that state's most recent inspection report. The report must be within 24 months of the date of application.

Q7) Am I required to adhere to minimum standards for wholesale distributors and current good manufacturing practices?

Yes. The Board adopted the following resolution on May 6, 2015:

Section 4729-16-02 of the Ohio Administrative Code requires an entity that provides, without a patient specific prescription, a non-patient specific sterile compounded drug preparation for human use only, if the following conditions apply:

(1) The entity is registered with the United States food and drug administration as an outsourcing facility pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (11/27/2013); and

(2) The entity is licensed as a wholesale distributor of dangerous drugs with an outsourcing facility classification pursuant to section 4729.52 of the Revised Code. The entity must include a licensed pharmacist as the responsible person on the license.

In order to provide clarity regarding the approval of entities that seek licensure as a wholesale distributor of dangerous drugs with an outsourcing facility classification, the Board recognizes that these entities shall meet all of the following criteria:

- *Federal laws and regulations, including Current Good Manufacturing Practices as determined by the United States Food and Drug Administration.*
- *Minimum standards for entities licensed as wholesale distributors of dangerous drugs, including section 4729-9-16 of the Ohio Administrative Code.*

Questions

If you have questions, please do not hesitate to contact the Board directly. The most expedient way to have your questions answered will be to email the Board office utilizing the "CONTACT THE BOARD" selection along the left side of the website: <http://www.pharmacy.ohio.gov/contact.aspx>. Be sure to select "General Licensing Information" as your subject line.

For More Information

For more information about outsourcing facilities, please visit:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>